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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,635	03/02/2004	Joseph Rock	US010382A	3051

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
PATEL, NATASHA	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,635	ROCK ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9,10,12-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9,10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 11/07/07 has been received and considered. By this amendment, Claim 1 has been amended and Claims 4, 7-8, 11, 15, and 17-25 remain cancelled. Thus, Claims 1-3, 5-6, 9-10, 12-14, and 16 are pending in the application.

Response to Arguments

1. Applicant's arguments filed 11/07/07 have been fully considered but they are not persuasive. Applicant discloses that the Vesely sheath's low level ultrasonic tracking signals are far removed from the high energy pulses used for cardiac stimulation (see page 7 of Arguments). However, Bilof already discloses a sheath substitution (see protective sheet 76) that has the conductors that are more capable of cardiac stimulation. Vesely is simply used to show that a sheath can be used instead of a sheet. In addition, the claim language "slidably cover the distal transesophageal portion" is still met by Vesely even if the sheath in Vesely is not closed at the distal end because the sheath simply has to exist somewhere along the distal portion. Furthermore, Vesely discloses that the distal end can be closed (see Figure 1 and col. 3, lines 44-45). Vesely discloses the transducers and conductors are embedded into the sheath (see col. 3, lines 51-53). Vesely discloses those same transducers and conductors perform the tracking and imaging functions (see col. 4, lines 9-12). Thus, it would have been obvious that in the embodiment, where the sheath is closed at the distal end, diagnostic tasks can still be carried out. As for stimulation, Bilof's protective sheet 76 was already shown to be capable of doing that along with the diagnostics. In summary, Bilof's protective sheet has all the capabilities required by Claim 1 except that it was not in

sheath form. Vesely's protective component was in sheath form. It would have been obvious to try and use this sheath form with Bilof's invention Vesely's sheath could be easily assembled onto the instrument, manipulated, and removed (see col. 5, lines 7-15).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5, 9, 12-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) in view of Vesely (US Patent 5,830,144).

4. Regarding Claim 1, Bilof discloses a system providing cardiac stimulation in combination with an endoscopic imaging probe (see col. 1, lines 50-51), comprising: a cardiac stimulation electrical conductor (see conducting member 36a; col. 3, lines 39-40); and an electrical cable (see cable 44; col. 3, lines 54-56), attached to the cardiac stimulation electrical conductor (see Figure 6), and adapted to be connected to an external defibrillator (see external defibrillator 50 or 102; col. 3, lines 56-66 and col. 6, lines 22-29). Bilof discloses a disposable, removable protective sheet affixed to the endoscopic imaging probe (see sheet member 76; col. 5, lines 33-44), wherein the cardiac stimulation electrical conductor (see conductor 66a or 36a) are integrated with the protective sheet (see Figure 8). Furthermore, since protective sheet 76 only extends

up to plastic extension member 40, cable 44 is not protected by the sheet (see Figure 6). However, Bilof does not disclose that the protective sheet forms a sheath, which by definition requires some type of enveloping structure or enclosing cover. Nevertheless, sheaths are well known in the medical lead art. For example, Vesley discloses a disposable, removable sheath of a flexible membrane material (see tracking data sheath 20, 20', 100; col. 2, lines 56-60 and 65-67) sized to slidably cover (see col. 5, lines 13-15) the distal transesophageal portion of the endoscopic imaging probe (see col. 1, lines 27-30 and Figure 3) and permit transesophageal ultrasonic imaging by the endoscopic imaging probe within the sheath (see col. 4, lines 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to use Vesely's tracking data sheath with Bilof's invention because Vesely teaches that doing so allows for *quickly* and easily modifying an instrument to include tracking capabilities that are necessary to provide therapy in a specific location (see col. 2, lines 50-53).

5. Regarding Claim 2, Bilof discloses a connector receiving the cable and adapted to connect the cable to the external defibrillator (see switch 46; col. 3, lines 56-63 and Figure 6); and a transthoracic pad connected to the external defibrillator for the cardiac stimulation (see col. 6, lines 28-35; Figure 11).

6. Regarding Claim 3, Bilof discloses a second cardiac stimulation electrical conductor (see conducting member 36b or 66b) located on the sheath, wherein an electrical path for cardiac stimulation is provided between the first and second conductors (see electrical connector 40; col. 3, lines 46-54).

7. Regarding Claim 5, Bilof discloses that the probe is insertable through a mouth into an esophagus of a patient (see col. 4, lines 24-25). Bilof also discloses an insulation type coating (see col. 5, lines 34-38) to protect the probe from damage (see col. 5, lines 36-38). The fact that the coating is insulative inherently requires that it comprises a suitable dielectric strength to protect the probe from damage by energy applied during the cardiac stimulation. Bilof does not disclose that this insulative coating is on the sheath. Vesley discloses a disposable, removable sheath of a flexible membrane material (see tracking data sheath 20, 20', 100; col. 2, lines 56-60 and 65-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to use Vesely's tracking data sheath instead of just a protective sheet because Vesely teaches that doing so allows for *quickly* and easily modifying an instrument to include tracking capabilities that are necessary to provide therapy in a specific location (see col. 2, lines 50-53). The examiner considers that slipping a sheath onto the probe is quicker than wrapping a protective sheet around it, similar to the difference between placing an object in a bag and gift wrapping it.

8. Regarding Claim 9, Bilof discloses at least one of the first and second conductors comprises a plurality of electrically connected conductors (see conducting members 36c-36f; col. 3, lines 40-50).

9. Regarding Claims 12 and 13, Bilof discloses that the cardiac stimulation comprises cardioversion, defibrillation or pacing in the atria and the ventricles of a subject (see col. 4, lines 37-39). The examiner considers that the heart H includes both atria and ventricles.

10. Regarding Claim 14, Bilof discloses that the cardiac stimulation comprises cardioversion, defibrillation or pacing of any of a plurality of pacemaker sites within a heart of a subject (see col. 3, lines 62-66 and col. 4, lines 53-59). The examiner considers that since the probe has multiple electrodes (see electrodes 22-32), a pair of electrodes is selected to carry out stimulation, and the electrodes are spaced apart from one another, then a plurality of sites must necessarily be stimulated.

11. Regarding Claim 16, Bilof discloses that the transthoracic pad is positioned over a thorax of a subject (see Figure 11).

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) and Vesely (US Patent 5,830,144) in view of Pless et al. (US Patent 4,640,298).

13. Regarding Claim 6, Bilof does not disclose an inflatable balloon. However, Pless discloses a similar esophageal probe that has an insulating sheath (see sheath 3; col. 5, line 43) further comprising an inflatable balloon (see either balloon 4Y or 4Z) positioned behind the conductor (see electrode material 5 in Figure 2) closing a gap between the esophagus and the sheath and pushing the conductor against a wall of the esophagus (see col. 4, lines 59-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Pless's inflatable balloon configuration in order to achieve the desired close contact between electrodes and the heart, thereby reducing current intensity and potential differences as taught by Pless (see col. 3, lines 12-16).

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bilof et al. (US Patent 5,191,885) and Vesely (US Patent 5,830,144) in view of Crowley (US Patent 5,588,432).

15. Regarding Claim 10, Bilof discloses a disposable, removable protective sheet affixed to the endoscopic imaging probe (see sheet member 76; col. 5, lines 33-44). Bilof does not disclose a sheath. Vesely discloses a sheath, but does not explicitly disclose that it is acoustically transparent. Crowley teaches catheter construction using acoustically transparent conductors for the purpose of enabling sensing and stimulation of tissue while not obstructing the monitoring of the tissues acoustically. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acoustically transparent conductors in the modified Bilof system in order to avoid compromised acoustically monitoring results that fail to disclose the impact of the acoustical testing on all the tissue in the test site (see col. 14, lines 31-36).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. (US Patent 6,980,865) which shows that a sheath can be slid out of the way even if the end of the sheath were closed (see col. 25, lines 34-46).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Natasha N Patel
Patent Examiner
Art Unit 3766

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
January 29, 2008